

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Vargas, Jaime; et. al.
Assignee: Cardica, Inc.
Title: Method for Sutureless Connection of Vessels
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Examiner: Woo, Julian W. Group Art Unit: 3731
Docket No.: 144

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Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF UNDER 37 CFR §41.37

This Reply Brief is prepared and submitted pursuant to the Examiner's Answer mailed on
June 25, 2008.

I. STATUS OF CLAIMS

Claims 1-3 and 7-22 stand finally rejected. These claims are set forth in the appendix attached hereto.

Claims 4-6 have been canceled, and as a result are not set forth in the appendix attached hereto.

II. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

A. Claims 1-15

Independent claim 1 stands finally rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,461,320 to Yencho et. al. (“Yencho”). Dependent claims 2-3, 14, 15, 21 and 22 also stand rejected under Yencho. Independent claim 1 also stands finally rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,113,612 to Swanson et. al. (“Swanson”). Dependent claims 7-13, 16-20 and 22 also stand finally rejected under Swanson.

III. ARGUMENTS

Claim 1 claims “a method of forming an anastomosis between a graft vessel and a target vessel, each vessel having a lumen therein and a wall around the lumen.” That method requires, among other steps, “providing an anastomosis device and an expander...manipulating said anastomosis device to form a first flange therein, said first flange positioned in the lumen of the target vessel and spaced apart from the wall of the target vessel; wherein said manipulating includes translating said expander relative to said anastomosis device, and wherein said manipulating completely forms said first flange; and moving said first flange into contact with the wall of the target vessel after said manipulating is complete.” (emphasis added).

The Examiner’s Answer succinctly and clearly sets forth a primary issue in this appeal, by contending that “a complete flange exists within the lumen of the target vessel (and spaced from the vessel wall) upon even an initial, minute deformation of the deformable section.”¹ That is, at any stage in the formation of the claimed first flange, a complete flange has been formed.

This position of the Examiner’s Answer is incorrect for at least three separate reasons. First, such a construction improperly reads out the limitation of “completely” from the claim phrase “completely forms,” as well as the limitation of “complete” from the claim phrase “after said manipulating is complete.” MPEP 2131 sets forth the legal standard of anticipation under 35 U.S.C. §102: “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”² That is, MPEP 2131 requires that “each and every element” of the claim be considered. By interpreting any stage in the formation of the complete first flange as being a complete flange itself, the Answer reads out the limitation of “completely” such that “each and every element” of the claim is not considered under MPEP 2131.

¹ *Id.*; page 5, lines 16-18.

² MPEP 2131 (*quoting Verdegaal Brothers v. Union Oil of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)) (emphasis added).

Second, the position that partially forming a flange is the same as completely forming a flange is contrary to logic. Even if it were not, the Answer fails to address the fact that claim 1 requires “manipulating” to continue until it “completely forms said first flange.” Only at that point does the claim allow “moving said first flange into contact with the wall of the target vessel.” If an arbitrary point “upon even an initial, minute deformation” is selected as a point at which the first flange is completely formed, that construction fails because manipulating would have to cease at that arbitrary point, prior to completely forming the first flange and “moving said first flange into contact with the wall of the target vessel.”

Third, even if the Answer were correct (which it is not) in its assertion that partially forming a flange is the same as completely forming a flange, it does not logically follow that a consequence of such partial formation of a flange is that “a complete flange...is spaced apart from the target vessel wall.” No technical reasoning is provided in support of that conclusion.

Both Yencho and Swanson describe connectors that shorten axially during the formation of a first flange, such that the first flange is only “completely formed” at such time that the first flange is in contact with the wall of the target vessel. Neither Yencho or Swanson expressly or inherently describe the claimed “manipulating [that] completely forms said first flange; and moving said first flange into contact with the wall of the target vessel after said manipulating is complete.” Thus, neither Yencho nor Swanson expressly or inherently describes each and every element claimed in claim 1, and as a result claim 1 is believed to be in condition for allowance. Claims 2-3 and 7-22 depend from claim 1, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

IV. CONCLUSION

For the above reasons, Applicants respectfully submit that the Final Action's rejection of pending claims 1-3 and 7-22 was unfounded. Accordingly, Applicants request that the rejection of those claims be reversed and that those claims be allowed.

Respectfully submitted,

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APPENDIX 1 -CLAIMS

1. A method of forming an anastomosis between a graft vessel and a target vessel, each vessel having a lumen therein and a wall around the lumen; the method comprising:
 - providing an anastomosis device and an expander;
 - connecting an end of the graft vessel to said anastomosis device;
 - delivering at least a portion of the anastomosis device into the lumen of the target vessel through an opening in the wall of the target vessel;
 - manipulating said anastomosis device to form a first flange therein, said first flange positioned in the lumen of the target vessel and spaced apart from the wall of the target vessel; wherein said manipulating includes translating said expander relative to said anastomosis device, and wherein said manipulating completely forms said first flange; and
 - moving said first flange into contact with the wall of the target vessel after said manipulating is complete.
2. The method of claim 1, wherein said connecting comprises everting an end of the graft vessel onto an end of said anastomosis device.
3. The method of claim 1, wherein said manipulating includes radially expanding at least a portion of said anastomosis device.
7. The method of claim 1, wherein said moving is substantially linear.
8. The method of claim 1, further comprising
 - providing a holder; and
 - connecting said anastomosis device to said holder, wherein at least a portion of said anastomosis device is separable from said holder.
9. The method of claim 8, wherein said moving is performed by moving said holder.
10. The method of claim 8, further comprising separating at least a portion of said anastomosis device from said holder after moving.

11. The method of claim 8, wherein said anastomosis device includes at least one tab at its proximal end, and wherein said connecting includes connecting at least one said tab to said holder.
12. The method of claim 1, further comprising manipulating said anastomosis device to form a second flange proximal to said first flange and positioned outside the target vessel.
13. The method of claim 12, wherein said second flange is at least partially in contact with the wall of the target vessel.
14. The method of claim 1, wherein said anastomosis device is at least partially tubular.
15. The method of claim 1, wherein said manipulating includes plastically deforming at least a portion of said anastomosis device.
16. The method of claim 1, wherein said anastomosis device is composed of stainless steel.
17. The method of claim 1, wherein said first flange includes a plurality of elements spaced apart from one another at their distal ends.
18. The method of claim 17, wherein said elements are arranged substantially radially symmetrically about the longitudinal axis of the anastomosis device.
19. The method of claim 17, wherein said connecting includes penetrating the graft vessel with at least one said element.
20. The method of claim 17, wherein said manipulating includes moving at least a portion of at least one said element away from at least a portion of a different said element.
21. The method of claim 1, wherein said anastomosis device is unitary.

22. The method of claim 1, wherein said translating comprises translating the distal end of said expander from a position within said anastomosis device to a position distal to and outside of said anastomosis device.